

REMARKS

The last Office Action from the Examiner is noted and regrettably, once again, claims that have previously been indicated as allowable have been reviewed, new art cited and the claims rejected. Such piecemeal examination is unduly burdensome and expensive for both the applicant and his attorney.

It is very unusual to reject a previously allowed claim. Full faith and credit should always be given to searches and actions previously issued unless there is clear error in the previous action. The Examiner should not take a new approach or attempt to reorient the point of view of previously set forth, or make anew search in the hope of finding some new art. See MPEP §706.04 and *Angen, Inc. v. Hoechst Marion Roussel, Inc.* 57 USPQ2d 1449 (U.S. D. Mass. 2001).

The four newly cited patents are no more pertinent to the present invention than those made of record earlier in the prosecution of this case.

Nevertheless, in order to achieve some resolution in this matter, the undersigned attorney and partner of the attorney who previously was responsible for this application has taken a fresh look at the disclosure, the invention and the prior art in order to draft a new parent claim that may meet the Examiner's approval.

New Claim 12, is the only parent claim in this application and it has been drafted in Jeppson form, *Ex parte Jeppson*, 1917 C.D. 61 (Commissioner of Patents - 1917). As such, the new parent claim sets forth the inventive step or improvement in the claim. "the improvement comprising..." The preamble of the claim being admitted prior art.

The previous parent Claim 1 and the dependent claims have been rejected under 35 USC § 103 as being unpatentable over the previously cited Alby patent taken in view of the newly cited U.S. Patent 5,725,528 to Errico. Additional prior art was also made of record but was not specifically relied upon in the formulation of any rejection of claims.

For ease in the understanding of Applicant's construction, four pictures from the Bricon AG (new owner by assignment of the application) are enclosed to assist the Examiner in properly understanding the inventive concept are enclosed. These pictures, show the different positions that the two plates may have. The fourth picture shows a rod and fixture that is not within the present description.

Certainly, at the first glance, Alby appears to be very similar to the features of the present invention, however, this is not really the case.

The Alby construction utilizes a plate design that was created at least as early as the 1980s by Arthur Steffee and is commonly known in the trade as the Steffee plate. This plate is also called a variable screw placement plate of

"VSP". Such plate utilizes a slotted plate configuration and arcuate recesses in the slots so that the plates could not slide along the screws which would defeat the proper fixation of the plate to the spine of the patient. (See U.S. Patent 4,655,199 - Figure 1).

The Steffee plate has been marketed in the United States by AcroMed and a number of problems caused the filing of many lawsuits against this company for injury and damage caused by the application of this plate construction.

A Steffee plate is used for example in U.S. Patent 4,836,196 which depicts a device very similar to that of Alby except for the eccentric bore. Figure 5 of Alby shows a typical representation of a Steffee plate with segments and hemispherical washers. The feature of the eccentric bore was the subject of the dependent claim 2 of the citation.

As can be easily seen, the degree of eccentricity of the Alby bore is restricted in the washer. More importantly, the rotational center of the screw is in the middle of the plate and is always in the longitudinal axis of the plate. When the lower washer is mounted, it cannot be turned. How can this be possible with the screw engaged in the bone, the mounted washer and the plate on top, all during a surgical procedure? When the screw is rotated, the upper washer will turn as well. Correction of the screw position is not possible because principally, the washers are fixed in position by the recesses

in the Steffee plates and no further movement along the plate is possible.

Accordingly, the screw can no longer be tilted to another angle, and it is fixed in its angular position. Apart from this, when the screw is fixed by the washers, these tend to move the screw to a more vertical position in relation to the plate since the screw extends through the bores of the lower and upper washer, leveling any effect from the eccentric bores. The washers cannot be moved in the longitudinal direction of the plate if at all, only the upper washer can be moved. How this can be accomplished remains a question. The position of the screw for the most part is fixed by the lower washer which cannot be moved. This positioning of the screw and washers results in tensions on the plate. It is not possible to make a distraction of the vertebrae. Such distraction is for the positioning of the vertebrae in the desired longitudinal position (adjustment of the interpedicular distance) by force.

Afterwards, the screw and plate system is finally fixed for completing the operative procedure and allowing healing in this position since the screw cannot be moved longitudinally of the plate due to the fact that the washers are fixed in the recesses. Rotational movements result in a tilting of the plate which is desired by Alby. (See Page 2, line 21).

It is possible that when the washers and the plate and screw of Alby are tightened, the hemispherical washers can change their position by the movement in the middle due to their eccentricity and the fact that they only have a line or point contact with the plate due to their shape. This change of position would result in a change of the angle of the screw and this would cause stress on the bone (pedicle) where the screw is engaged which would result in future pain for the patient.

From the comments noted above, the positioning and adjusting possibilities of the Alby system may appear to be acceptable, however, in actual orthopedic practice, they are more or less theoretical and are not actually realized.

The structure of the newly cited Errico patent has been carefully studied and the same does not allow free movement of the screw. The arrangement comprises several parts that have to be fixed. The screw is mounted to a rod and fixed in the desired longitudinal and angular position. The longitudinal position of the screw is effected by locking the screw to a rod coupling element 160 and fixing the rod coupling element at a desired longitudinal position on the rod. The stem part 120 is rotated on the hemispherical upper part 108 of the screw and fixed in the desired angular position thereto by means of a coupling element (cuff 130). Thus, free movement

for the positioning of the plate with respect to the screw is not possible because this would require loosening of another already fixed part. Hence a distraction is not possible.

It is the position of counsel and the inventor herein, that the combination of the rod system with a polyaxial screw of Errico with the plate system having a monoaxial screw as in Alby would not be obvious to one skilled in the art.

A polyaxial screw used in a Steffee plate would not result in positioning advantages because of the pre-fixing by the recesses of the plate and the inability to shift the screw in the lengthwise direction after a plate has been applied and a first or initial fixation has been effected. There is no suggestion in either reference to make the combination as set forth by the Examiner.

The spinal column support system according to the present invention, and as defined in new claim 12 differs in function from the cited prior art. It allows the free sliding of the screw respectively in the discs 6 and 8 in the elongated opening 4 in the longitudinal direction of the plate.

Therefor no steps nor predefined positions as in the case of the Steffee plate are present to hinder such sliding. The discs may be freely shifted and rotated, both yielding two free movement degrees. This will allow compensation of screw slant over a large range of degree slant in comparison to those of the Alby system. The plate is not tilted by these

movements. Since the discs are freely moveable, this compensation movement allows the avoidance of stresses between the screw and the plate. The discs do not have to be concentric. Thus, even if the screw is nearly fixed but the nut not yet applied and tightened, a residual ability to move is present, i.e. the screw and discs can be shifted. This allows distraction (longitudinal movement) of the vertebrae.

The system of the invention is not obvious to one skilled in the art. The discs are not hemispherical washers as in Alby. They are displaceable and specifically, they can be rotated and are freely moveable. See paragraph 22 of the printed publication. This is not true in Alby or the Steffee system. Errico does not include plates, hence this feature is not suggested by this citation.

Applicant's screw is axially moveable above the screw shaft, that is, it can be moved above the shaft part as described in paragraph 23 of the published application. The multi-axial form of the upper part of the screw allows the compensation of extremely inclined positions of the screw shaft. Whereas the screw is fixed with the shaft 20 in the bone at an angle from the vertical, its upper part 18 is accommodated in a rotationally moveable manner. Note paragraph 38 of the published application. Both screw parts, the upper as well as the lower, are moveable with respect to each other (see the beginning of paragraph 38 of the published application). The multi-axial construction of the bone screw

allows axial movement in the upper part, i.e. above the shaft. This movement is obtained by the moveable discs and it results in a vertical positioning of the upper screw part irrespective of the angular position of the lower screw part, i.e. the screw shaft.

The following should be taken into consideration. First, the screw is rotationally applied to the bone. Then, the plate is mounted. For optimum positioning of the plate, it is necessary to provide compensation for the screw orientations that are due to the shape of the bones and also to the present positions and orientations of the bones that may have to be redirected by the surgical procedure.

For this purpose, the screw is provided with a polyaxial configuration resulting in that above the shaft a joint is provided allowing rotation of the upper screw part so that such art can be rotated to such an angle that it will be more or less vertical with respect to the plate. By this measure, the orientation of the plate can be maintained as it should be and no stress is incurred between plate and screw. Rotation of the upper screw part and movement of the upper and lower discs is thus permitted. They can each be shifted in the longitudinal direction of the plate and can be rotated to allow various orientations of the screw parts that pass through the plate.

The positional height of the plate with respect to the bone mounted screw allows the bone to move nearer or further away from the plate. This distraction (movement of the screw along the longitudinal direction of the plate, allows movement of the vertebrae with respect to each other so that their can be properly corrected.

Both of these features; the free movability of the discs and the multi-axial structure of the screw allow the vertebrae distraction prior to finally tightening of the nut.

With regard to the *calotte bearing*, this element 30 is not actually a cap, but rather it is a fixture 26 called a calotte system in the medical field and in the application text. This fixture 26 comprises a calotte body 28 provided with the calotte bearing. The bearing is such that the bone screw shaft 20 is held freely moveable. The residual movability of the screw allows a small degree of compensations of movement and reduces any stresses in the vertebrae and plate mounting.

This feature of the calotte bearing is a matter of function and has nothing to do with the shape of the fixation element. The Errico system does not allow residual movability since the fixture of the parts requires a tight clamp or seat. Otherwise, the parts would not maintain their orientation and

position. Also Alby does not allow movability of the hemispherical discs, If the discs are moved, the orientation of the screw would change.

The new independent claim 12 the multi-axial structure of the bone screw is adequately set forth.

It should also be noted that Applicant's European patent was granted after consideration of the teachings of the Alby patent.

In view of the amendments and the remarks noted, *supra*, reconsideration of the application is respectfully solicited with a view to allowance of the remaining claims.

Respectfully submitted,



Donald L. Dennison
Reg. No. 19,920
Attorney for Applicant
Dennison, Schultz & MacDonald
1727 King Street
Suite 105
Alexandria, VA 22314
(703)837-9600 Ext. 15
ddennison@dennisonlaw.com

June 30, 2008